REMARKS

Claims 1-23 are pending in the application.

In the present amendment, claims 1, 3, and 15 are revised according to the Examiner's suggestions, namely identifying each recited ORF feature by its corresponding and disclosed nucleotide sequence. Claim 10 is amended for clarity by introducing the article "a". Claim 20 is amended to bring the typed format into line with the present amendments including the term "SEQ ID NO:". Claims 1 and 13 are cancelled. Claims 1 and 15 are further amended to recite the nucleic acid features as including "SEQ ID NO:5 or SEQ ID NO:9 (ORF 5), and SEQ ID NO:7 (ORF 7) of EAV, wherein ORF 2 is the nucleotide sequence as set forth in SEQ ID NO:2 or a functional variant thereof, wherein said variant carries nucleic acid exchanges, deletions or insertions which amount up to 10% of the nucleotide acids of the nucleotide sequences set forth in SEQ ID NO:2". No new matter has been introduced by these amendments, as support is found throughout the specification, for example, in paragraphs [0054], [0055], and [0061] (claims 1 and 15).

Accordingly, entry of these amendments is respectfully requested.

I. Claim Rejections Under 35 U.S.C. § 112, 2nd Paragraph

Claims 1-20 were rejected under § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully traverse this rejection.

Specifically, claim 1 was rejected for reciting "equine arterivirus", while the specification refers to "equine arteritis virus". The latter terminology is now included in currently amended claim 1. Therefore, Applicants submit that this rejection is rendered moot.

Claims 3 and 15 were rejected for not including a SEQ ID NO for the recited ORF elements, namely "ORF 1a, ORF 1b, ORF 3, ORF 4, ORF 6". Both claims 3 and 15 have been presently amended to refer to the disclosed SEQ ID NOs corresponding to each of the above-mentioned ORFs. Because claims 3 and 15 now properly recite the "SEQ ID NO" identifiers, Applicants submit that these claims, in addition to claims 2, 4-14, and 16-20 which are dependent therefrom, are clear and definite.

For the reasons outlined above, Applicants respectfully request that the present rejections under § 112, second paragraph, be reconsidered and withdrawn.

II. Rejection of Claims 1, 3-8, 10, 15-19, 24 and 25 Under 35 U.S.C. § 102(b)

Claims 1, 3-8, 10, 15-19, 24 and 25 were rejected as being anticipated by Tobiasch *et al.*, (2001) ("Tobiasch"). Applicants respectfully traverse this rejection.

Applicant's amended claim 1 recites a vaccine composition which is protective against equine arteritis virus (EAV) infections in horses and induces a cellular immune response. In the present amendment, Applicant has amended claim 1 to recite a vaccine composition *consisting of* open reading frame nucleic acids (ORF) 2, SEQ ID NO:5 or SEQ ID NO:9 (ORF 5), *and* SEQ ID NO:7 (ORF 7) of EAV, wherein ORF 2 is the nucleotide sequence as set forth in SEQ ID NO:2 or a functional variant thereof, wherein said variant carries nucleic acid exchanges, deletions or insertions which *amount up to 10%* of the nucleotide acids of the nucleotide sequences set forth in SEQ ID NO:2.

Furthermore, Applicant's amended independent claim 15 now recites a nucleic acid vector comprising nucleic acids consisting of the *same* open reading frame nucleic acids in a like amount as recited by claim 1.

Tobiasch describes a vaccine composition comprising an open reading frame both the nucleic acid (ORF) ORF 5 and ORF 7 (but not ORF 2) of EAV for the purposes of inducing an immune response by vaccination to thereby prevent EAV in horses (Table 2, Figure 5). Specifically, cDNA sequences derived from ORF 3, ORF 4, ORF 5, and ORF 7 were cloned into the expression vectors pCR3.1, pDisplay, and/orpcDNA3.1/HisC.

Claims 1, 3-8, 10, 15-19, 24 and 25 are simply not anticipated by Tobiasch, because this reference does not disclose a vaccine composition or a nucleic acid vector consisting of nucleic acid(s) encoding ORF 2, ORF 5 *and* ORF 7, wherein the ORF 2 (or a functional variant thereof, wherein said variant carries nucleic acid exchanges, deletions or insertions) exists *in an amount up to 10%* of the nucleotide acids of the nucleotide sequences set forth in SEQ ID NO:2.

Accordingly, Applicants respectfully submit that the above claims are not anticipated, and request that the Examiner reconsider and withdraw the present rejection under § 102(b).

III. **Rejection of Claims 1, 2, 4-10, 12, 14-19, 24 and 25 Under 35 U.S.C. § 102(a)**

Claims 1, 2, 4-10, 12, 14-19, 24 and 25 were rejected as being anticipated by Giese *et al.*, (2002) ("Giese"). Applicants respectfully traverse this rejection.

Applicants would like to point out to the Examiner that a request to recognize a "Claim of Priority under 35 U.S.C. § 119" was transmitted to the USPTO on October 4, 2006 by Applicant's former professional representative. The priority document is European Patent application EP 02002250.5 having a priority date of January 30, 2002 – thereby preceding the publication date of February 28, 2002 for the Giese reference. Because the subject matter of the present application is identical in scope to the corresponding European priority document, Applicants note that the Giese reference is no longer relevant as qualifying prior art with respect to the presently claimed invention.

Accordingly, Applicants respectfully submit that the above claims can not be anticipated, and request that the Examiner reconsider and withdraw the present rejection under § 102(a).

IV. **Rejection of Claims 1, 3-8, 10, 13, 15-20, 24 and 25 Under 35 U.S.C. §§ 102(b)/103**

Claims 1, 3-8, 10, 13, 15-20, 24 and 25 were rejected as being anticipated by Tobiasch *et al.*, (2001) ("Tobiasch"). Applicant respectfully traverses this rejection.

With respect to the rejection under U.S.C. § 102(b) directed to novelty, we refer the Examiner to our arguments presented in Section II above.

Turning to the rejection under U.S.C. § 103, the Examiner notes that Tobiasch discloses various cDNA and amino acid sequences derivable from current GenBank, EMBL, and SwissProt database sequence entries (matching the presently disclosed sequences for ORF 2, ORF 5, ORF 7) and asserts that known molecular cloning methods can be used to clone these EAV ORFs into the same expression vectors to thereby arrive at the presently claimed invention. Applicant respectfully traverses this rejection.

Applicants' independent claims 1 and 15 recite a vaccine composition and nucleic acid vector, respectively, which is protective against equine arteritis virus (EAV) infections in horses and induces a cellular immune response. Presently, Applicant has amended claim 1 to recite a vaccine composition *consisting of* an ORF 2 sequence, wherein the ORF 2 is the nucleotide

sequence as set forth in SEQ ID NO:2 or a functional variant thereof, wherein said variant carries nucleic acid exchanges, deletions or insertions which *amount up to 10%* of the nucleotide acids of the nucleotide sequences set forth in SEQ ID NO:2 – and has introduced a parallel amendment into claim 15.

The disclosure of Tobiasch is noted above, and is also described in Section II.

Claims 1, 3-8, 10, 13, 15-20, 24 and 25 are not *prima facie* obvious over Tobiasch, most importantly because Tobiasch does not teach the novel use of ORF 2 in a vaccine composition, or even any combination of ORF 2, ORF 5 and ORF 7 in a vaccine or a nucleic acid vector composition. The present specification clearly shows that a vaccine comprising these three ORFs in combination, in particular due to the presence of ORF 2, can induce a surprising neutralizing antibody response (e.g. TABLE 8). Nowhere in the Tobiasch disclosure is there any information to teach, motivate or even suggest to the skilled person that the addition of ORF 2 DNA results in the induction of antibodies specific for the polypeptide encoded by ORF2. As clearly shown in Tables 19 and 20 of the instant application (e.g. EXAMPLE 2), the polypeptide encoded by ORF 2 induces a pronounced cytotoxic T cell response in some of the vaccinated animals to thereby enhance the efficacy of the vaccination process. The Tobiasch disclosure is completely silent on designing a composition to provide the particular claimed characteristics, namely, to induce this pronounced cytotoxic response due to the presence of the sequence coding for ORF 2.

Therefore, because *prima facie* obviousness and anticipation of present claims 1, 3-8, 10, 13, 15-20, 24 and 25 has not been established, these claims are not obvious in view of or anticipated by the cited reference. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the present rejection under §§ 102(b)/103.

V. Rejection of Claims 1, 3-8, 10, 11, 15-19, 24 and 25 Under 35 U.S.C. § 103(a)

Claims 1, 3-8, 10, 11, 15-19, 24 and 25 were rejected as being anticipated by Tobiasch *et al.*, (2001) ("Tobiasch") in view of Krieg *et al.* (1998) ("Krieg"). Applicants respectfully traverse this rejection.

For an overview of the Tobiasch reference, we kindly refer the Examiner to our previous discussion provided in Sections IV and II above.

Krieg provides a general overview of the effects of CpG as an adjuvant in DNA vaccine compositions in order to enhance an immune response.

Independent claims 1 and 15 (and all associated-dependent claims and independent claims reciting the features thereof) are not *prima facie* obvious over Tobiasch in view of Krieg, at least because the references, even in combination, do not teach or suggest a vaccine composition or nucleic acid vector *consisting of* nucleic acid(s) encoding ORF 2, ORF 5 *and* ORF 7, wherein the ORF 2 (or a functional variant thereof, wherein said variant carries nucleic acid exchanges, deletions or insertions) exists *in an amount up to 10%* of the nucleotide acids of the nucleotide sequences set forth in SEQ ID NO:2. As already explained, the ORF 2 nucleic acid sequence was not known in the art as a nucleic acid vaccine at Applicant's priority date, therefore the skilled person could only derive the ORF 2 sequence for use in a vaccine composition using inventive skill.

Consequently, there would be no motivation for one of ordinary skill in the art to combine the teachings of the cited references. The Office Action suggests that one of ordinary skill in the art would be motivated to combine, modify the teachings of Tobiasch, disclosing a DNA vaccine composition against, with the teachings of Krieg, by adding CpG dinucleotides in order to achieve an essential endogenous adjuvant activity for the EAV ORF vaccine, while increasing the efficacy of the EAV vaccine compositions. However, and to emphasize, because Tobiasch itself fails to describe the ORF 2 sequence or any important features thereof relating to the demonstrated enhanced cytotoxic effect of this ORF in a vaccine composition, one of ordinary skill in the art reading Tobiasch could not reasonably consider applying the methods of Krieg to arrive at the claimed invention.

Accordingly, *prima facie* obviousness has not been established, and independent claims 1 and 15 are not obvious in view of the cited references alone or in combination. Associated-dependent claims and independent claims reciting the features of claims 1 or 15 are not obvious for at least the same reasons as the independent claims 1 and 15. Therefore, Applicant respectfully requests that the present rejection under § 103 be reconsidered and withdrawn.

IX. Conclusion

In view of the amendment and arguments set forth above, Applicants kindly submit that the objections and rejections contained in the Office Action mailed on July 14, 2006 have been overcome, and that the pending claims are in condition for allowance.

Please charge the $795.00 fee as set forth in Fee Code 1254/2254 per 37 C.F.R. 1.17(a)(4) for the "Extension for Response within Fourth Month" (small entity) which is submitted herewith on enclosed Form PTO-2038. No other fees are believed to be due in connection with this correspondence.

The Examiner is encouraged to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,

Dated: December 13, 2006

Stacey J. Farmer
Reg. No. 42,526

GRUND INTELLECTUAL PROPERTY GROUP
Nikolaistrasse 15
D-80802 Munich
GERMANY

+ 49 (89) 54 80 19 - 0 (telephone)
+ 49 (89) 54 80 19 - 10 (facsimile)